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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. WATSON LABORATORIES, INC., Defendant.	)	Civil Action No. 2-14-cv-07757

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF WATSON LABORATORIES, INC.

Defendant Watson Laboratories, Inc. ("Watson"), by and through its counsel, answers the Complaint of Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Plaintiffs") with the following answers, affirmative defenses, and counterclaims. Counts VIII-XIV of Plaintiffs' Complaint are the subject of a motion to dismiss filed previously by Watson. Watson denies all allegations not expressly admitted herein.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Watson's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Jazz Pharmaceuticals' XYREM® drug product prior to the expiration of United States Patent Nos. 6,472,431 (the "'431 patent"), 6,780,889 (the '889 patent"), 7,262,219 (the "'219 patent"), 7,851,506 (the "'506 patent"), 8,263,650 (the "'650 patent"), 8,324,275 (the "'275 patent"), 8,461,203 (the "'203 patent"), 7,668,730 (the '730 patent"), 7,765,106 (the '106 patent"), 7,765,107 (the '107 patent"), 7,895,059 (the "'059 patent"), 8,457,988 (the '988 patent"), 8,589,182 (the '182 patent"), 8,731,963 (the '963 patent"), and 8,772,306 (the '306 patent") owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit").

ANSWER:

Watson admits that the Complaint purports to state an action arising under 35 U.S.C. §100, *et seq.*, for alleged infringement of United States Patent Nos. 6,472,431 ("the '431 patent"), 6,780,889 ("the '889 patent"), 7,262,219 ("the '219 patent"), 7,851,506 ("the '506 patent"), 8,263,650 ("the '650 patent"), 8,324,275 ("the '275 patent"), 8,461,203 ("the '203 patent"), 7,668,730 ("the '730 patent"), 7,765,106 ("the '106 patent"), 7,765,107 ("the '107 patent"), 7,895,059 ("the '059 patent"), 8,457,988 ("the '988 patent"), 8,589,182 ("the '182 patent"), 8,731,963 ("the '963 patent"), and 8,772,306 ("the '306 patent") (collectively, "the patents-in-suit"). Watson admits that it filed an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") regulatory approval of a generic version of 500 mg/mL sodium oxybate oral solution ("Watson's Proposed Product"). Watson denies any remaining allegations of this paragraph.

THE PARTIES

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

ANSWER:

Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

3. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at One Burlington Road, Fourth Floor, Connaught House, Dublin, Ireland 4.

ANSWER:

Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

4. On information and belief, defendant Watson is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

ANSWER:

Watson admits the allegations of this paragraph.

5. On information and belief, Watson develops numerous generic drugs for sale and use throughout the United States, including in this Judicial District. Watson has litigated patent cases in this District in the past without contesting personal jurisdiction, and, in at least some of those actions, Watson has asserted counterclaims.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson does not contest this Court exercising jurisdiction over Watson for the purposes of this action only. Watson denies any remaining allegations of this paragraph.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits only that this Court has subject matter jurisdiction over claims asserted against Watson under 35 U.S.C. § 271(e)(2)(A). Watson denies that this Court has subject matter jurisdiction over any other claims asserted against it. Watson denies any remaining allegations of this paragraph.

7. This Court has personal jurisdiction over Watson by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Watson has its principal place of business in Parsippany, New Jersey, conducts business in this District, purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Watson has customers in the State of New Jersey. Further, on information and belief, Watson is registered to conduct business in the State of New Jersey.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson does not contest this Court exercising jurisdiction over Watson for the purposes of this action only. Watson denies any remaining allegations of this paragraph.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. Watson states that it is not contesting venue in this district for the purposes of this action only. Watson denies any remaining allegations of this paragraph.

THE PATENTS-IN-SUIT

9. On October 29, 2002, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '431 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '431 patent is attached hereto as Exhibit A.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit A appears to be a copy of the '431 patent. Watson states that the '431 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ’431 patent states, on its face, a title of “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy” and an issuance date of October 29, 2002. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ’431 patent, and therefore denies the same. Watson denies that the ’431 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

10. On August 24, 2004, the USPTO duly and lawfully issued the ‘889 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ‘889 patent is attached hereto as Exhibit B.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit B appears to be a copy of the ‘889 patent. Watson states that the ’889 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ’889 patent states, on its face, a title of “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy” and an issuance date of August 24, 2004. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘889 patent, and therefore denies the same. Watson denies that the ’889 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

11. On August 28, 2007, the USPTO duly and lawfully issued the ‘219 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ‘219 patent is attached hereto as Exhibit C.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit C appears to be a copy of the '219 patent. Watson states that the '219 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the '219 patent states, on its face, a title of "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy" and an issuance date of August 28, 2007. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the '219 patent, and therefore denies the same. Watson denies that the '219 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

12. On December 14, 2010, the USPTO duly and lawfully issued the '506 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '506 patent is attached hereto as Exhibit D.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit D appears to be a copy of the '506 patent. Watson states that the '506 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the '506 patent states, on its face, a title of "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy" and an issuance date of December 14, 2010. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the '506 patent, and therefore denies the same. Watson denies that the '506 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

13. On September 11, 2012, the USPTO duly and lawfully issued the '650 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '650 patent is attached hereto as Exhibit E.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit E appears to be a copy of the '650 patent. Watson states that the '650 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the '650 patent states, on its face, a title of "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy" and an issuance date of September 11, 2012. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the '650 patent, and therefore denies the same. Watson denies that the '650 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

14. On December 4, 2012, the USPTO duly and lawfully issued the '275 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '275 patent is attached hereto as Exhibit F.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit F appears to be a copy of the '275 patent. Watson states that the '275 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the '275 patent states, on its face, a title of "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy" and an issuance date of December 4, 2012. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘275 patent, and therefore denies the same. Watson denies that the ‘275 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

15. On June 11, 2013, the USPTO duly and lawfully issued the ‘203 Patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ‘203 patent is attached hereto as Exhibit G.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit G appears to be a copy of the ‘203 patent. Watson states that the ‘203 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘203 patent states, on its face, a title of “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy” and an issuance date of June 11, 2013. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘203 patent, and therefore denies the same. Watson denies that the ‘203 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

16. On February 23, 2010, the USPTO duly and lawfully issued the ‘730 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ‘730 patent is attached hereto as Exhibit H.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit H appears to be a copy of the ‘730 patent. Watson states that the ‘730 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘730 patent states, on its face, a title of “Sensitive Drug Distribution System and Method” and an issuance date of February 23,

2010. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘730 patent, and therefore denies the same. Watson denies that the ‘730 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

17. On July 27, 2010, the USPTO duly and lawfully issued the ‘106 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ‘106 patent is attached hereto as Exhibit I.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit I appears to be a copy of the ‘106 patent. Watson states that the ‘106 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘106 patent states, on its face, a title of “Sensitive Drug Distribution System and Method” and an issuance date of July 27, 2010. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘106 patent, and therefore denies the same. Watson denies that the ‘106 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

18. On July 27, 2010, the USPTO duly and lawfully issued the ‘107 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ‘107 patent is attached hereto as Exhibit J.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit J appears to be a copy of the ‘107 patent. Watson states that the ‘107 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘107 patent states, on its face, a title of “Sensitive Drug Distribution System and Method” and an issuance date of July 27, 2010. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘107 patent, and therefore denies the same. Watson denies that the ‘107 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

19. On February 22, 2011, the USPTO duly and lawfully issued the ‘059 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ‘059 patent is attached hereto as Exhibit K.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit K appears to be a copy of the ‘059 patent. Watson states that the ‘059 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘059 patent states, on its face, a title of “Sensitive Drug Distribution System and Method” and an issuance date of February 22, 2011. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘059 patent, and therefore denies the same. Watson denies that the ‘059 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

20. On June 4, 2013, the USPTO duly and lawfully issued the ‘988 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ‘988 patent is attached hereto as Exhibit L.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit L appears to be a copy of the ‘988 patent. Watson states that the ‘988 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘988 patent states, on its face, a title of “Sensitive Drug Distribution System and Method” and an issuance date of June 4, 2013. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘988 patent, and therefore denies the same. Watson denies that the ‘988 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

21. On November 19, 2013, the USPTO duly and lawfully issued the ‘182 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ‘182 patent is attached hereto as Exhibit M.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit M appears to be a copy of the ‘182 patent. Watson states that the ‘182 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘182 patent states, on its face, a title of “Sensitive Drug Distribution System and Method” and an issuance date of November 19, 2013. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘182 patent, and therefore denies the same. Watson denies that the ‘182 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

22. On May 20, 2014, the USPTO duly and lawfully issued the ‘963 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ‘963 patent is attached hereto as Exhibit N.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit N appears to be a copy of the ‘963 patent. Watson states that the ‘963 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘963 patent states, on its face, a title of “Sensitive Drug Distribution System and Method” and an issuance date of May 20, 2014. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘963 patent, and therefore denies the same. Watson denies that the ‘963 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

23. On July 8, 2014, the USPTO duly and lawfully issued the ‘306 patent, entitled “Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters.” A copy of the ‘306 patent is attached hereto as Exhibit O.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson admits that Exhibit O appears to be a copy of the ‘306 patent. Watson states that the ‘306 patent speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Watson admits that the ‘306 patent states, on its face, a title of “Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters” and an issuance date of July 8, 2014. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the ‘306 patent, and therefore denies the same. Watson denies that the ‘306 patent was duly and legally issued. Watson denies any remaining allegations of this paragraph.

THE XYREM® DRUG PRODUCT

24. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM®. The claims of the patents-in-suit cover, inter alia, pharmaceutical compositions containing sodium oxybate, and methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patents-in-suit.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning ownership of New Drug Application ("NDA") No. 21-196, and therefore denies the same. Watson further states that the claims of the patents-in-suit speak for themselves, and Watson denies deny the allegations in this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe the patents-in-suit. Watson lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the patents-in-suit, and therefore denies the same. Watson denies any remaining allegations of this paragraph.

25. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, and '306 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

ANSWER:

Watson states that the Orange Book speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe the Orange Book. Watson denies any remaining allegations of this paragraph.

26. The labeling for XYREM® instructs and encourages physicians, other healthcare workers, and patients to administer XYREM® according to the methods claimed in several of the patents-in-suit.

ANSWER:

Watson states that the labeling for XYREM® speaks for itself, and Watson denies the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe the labeling for XYREM®. Watson denies any remaining allegations of this paragraph.

ACTS GIVING RISE TO THIS SUIT

27. Pursuant to Section 505 of the FFDCA, Watson filed ANDA No. 204952 ("Watson's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Watson's Proposed Product"), before the patents-in-suit expire.

ANSWER:

Watson admits that it filed Abbreviated New Drug Application ("ANDA") No. 204952 ("Watson's ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") regulatory approval of Watson's Proposed Product. Watson denies any remaining allegations of this paragraph.

28. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Watson has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Watson's Paragraph IV Certification"), alleging that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, and '306 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA.

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

29. No earlier than October 29, 2014, Jazz Pharmaceuticals received written notice of Watson's Paragraph IV Certification ("Watson's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Watson's Notice Letter alleged that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, and '306 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA. Watson's Notice Letter also informed Jazz Pharmaceuticals that Watson's seeks approval to market Watson's Proposed Product before the patents-in-suit expire.

ANSWER:

Watson admits that it sent a letter dated October 29, 2014 concerning Watson's ANDA to Plaintiffs. Watson states that the letter speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the letter. Watson denies any remaining allegations of this paragraph.

COUNT I: INFRINGEMENT OF THE '431 PATENT

30. Plaintiffs repeat and reallege the allegations of paragraphs 1-29 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

31. Watson, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '431 patent. Watson's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

32. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution prior to the expiration of the '431 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson denies the allegations of this paragraph.

33. There is a justiciable controversy between the parties hereto as to the infringement of the '431 patent.

ANSWER:

Watson admits the allegations of this paragraph.

34. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '431 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

35. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '431 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '431 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

36. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '431 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '431 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

37. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson's infringement of the '431 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

38. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

39. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

COUNT II: INFRINGEMENT OF THE '889 PATENT

40. Plaintiffs repeat and reallege the allegations of paragraphs 1-39 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

41. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '889 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

42. There is a justiciable controversy between the parties hereto as to the infringement of the '889 patent.

ANSWER:

Watson admits the allegations of this paragraph.

43. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '889 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

44. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '889 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '889 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

45. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '889 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '889 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

46. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson's infringement of the '889 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

47. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

48. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

COUNT III: INFRINGEMENT OF THE '219 PATENT

49. Plaintiffs repeat and reallege the allegations of paragraphs 1-48 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

50. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '219 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

51. There is a justiciable controversy between the parties hereto as to the infringement of the '219 patent.

ANSWER:

Watson admits the allegations of this paragraph.

52. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '219 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

53. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '219 patent under 35 U.S.C. § 271(b) by making, using, offering

to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '219 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

54. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '219 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '219 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

55. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson's infringement of the '219 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

56. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

57. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

COUNT IV: INFRINGEMENT OF THE '506 PATENT

58. Plaintiffs repeat and reallege the allegations of paragraphs 1-57 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

59. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '506 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

60. There is a justiciable controversy between the parties hereto as to the infringement of the '506 patent.

ANSWER:

Watson admits the allegations of this paragraph.

61. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '506 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

62. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '506 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '506 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

63. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '506 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '506 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

64. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson's infringement of the '506 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

65. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

66. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

COUNT V: INFRINGEMENT OF THE '650 PATENT

67. Plaintiffs repeat and reallege the allegations of paragraphs 1-66 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

68. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '650 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

69. There is a justiciable controversy between the parties hereto as to the infringement of the '650 patent.

ANSWER:

Watson admits the allegations of this paragraph.

70. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '650 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

71. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '650 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '650 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

72. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '650 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '650 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

73. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson's infringement of the '650 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

74. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

75. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

COUNT VI: INFRINGEMENT OF THE '275 PATENT

76. Plaintiffs repeat and reallege the allegations of paragraphs 1-75 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

77. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '275 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

78. There is a justiciable controversy between the parties hereto as to the infringement of the ‘275 patent.

ANSWER:

Watson admits the allegations of this paragraph.

79. Unless enjoined by this Court, upon FDA approval of Watson’s ANDA, Watson will infringe the ‘275 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson’s Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

80. Unless enjoined by this Court, upon FDA approval of Watson’s ANDA, Watson will induce infringement of the ‘275 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson’s Proposed Product in the United States. On information and belief, upon FDA approval of Watson’s ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the ‘275 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

81. Unless enjoined by this Court, upon FDA approval of Watson’s ANDA, Watson will contributorily infringe the ‘275 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson’s Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson’s Proposed Product is especially adapted for a use that infringes the ‘275 patent and that there is no substantial non-infringing use for Watson’s Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

82. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson’s infringement of the ‘275 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

83. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

84. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

COUNT VII: INFRINGEMENT OF THE '203 PATENT

85. Plaintiffs repeat and reallege the allegations of paragraphs 1-84 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

86. Watson, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '203 patent. Watson's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

87. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution prior to the expiration of the '203 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson denies the allegations of this paragraph.

88. There is a justiciable controversy between the parties hereto as to the infringement of the '203 patent.

ANSWER:

Watson admits the allegations of this paragraph.

89. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '203 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

90. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '203 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '203 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

91. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '203 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '203 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

92. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson's infringement of the '203 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

93. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

94. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

COUNT VIII: INFRINGEMENT OF THE '730 PATENT

ANSWER:

Pursuant to Fed. R. Civ. P. 12(b)(6), Watson has filed a motion to dismiss this Count for failure to state a claim upon which relief may be granted. Because this Count is the subject of Watson's pending motion to dismiss, no further response is required. To the extent a response is deemed required, Watson denies the allegations of this count.

COUNT IX: INFRINGEMENT OF THE '106 PATENT

ANSWER:

Pursuant to Fed. R. Civ. P. 12(b)(6), Watson has filed a motion to dismiss this Count for failure to state a claim upon which relief may be granted. Because this Count is the subject of Watson's pending motion to dismiss, no further response is required. To the extent a response is deemed required, Watson denies the allegations of this count.

COUNT X: INFRINGEMENT OF THE '107 PATENT

ANSWER:

Pursuant to Fed. R. Civ. P. 12(b)(6), Watson has filed a motion to dismiss this Count for failure to state a claim upon which relief may be granted. Because this Count is the subject of Watson's pending motion to dismiss, no further response is required. To the extent a response is deemed required, Watson denies the allegations of this count.

COUNT XI: INFRINGEMENT OF THE '059 PATENT

ANSWER:

Pursuant to Fed. R. Civ. P. 12(b)(6), Watson has filed a motion to dismiss this Count for failure to state a claim upon which relief may be granted. Because this Count is the subject of

Watson's pending motion to dismiss, no further response is required. To the extent a response is deemed required, Watson denies the allegations of this count.

COUNT XII: INFRINGEMENT OF THE '988 PATENT

ANSWER:

Pursuant to Fed. R. Civ. P. 12(b)(6), Watson has filed a motion to dismiss this Count for failure to state a claim upon which relief may be granted. Because this Count is the subject of Watson's pending motion to dismiss, no further response is required. To the extent a response is deemed required, Watson denies the allegations of this count.

COUNT XIII: INFRINGEMENT OF THE '182 PATENT

ANSWER:

Pursuant to Fed. R. Civ. P. 12(b)(6), Watson has filed a motion to dismiss this Count for failure to state a claim upon which relief may be granted. Because this Count is the subject of Watson's pending motion to dismiss, no further response is required. To the extent a response is deemed required, Watson denies the allegations of this count.

COUNT XIV: INFRINGEMENT OF THE '963 PATENT

ANSWER:

Pursuant to Fed. R. Civ. P. 12(b)(6), Watson has filed a motion to dismiss this Count for failure to state a claim upon which relief may be granted. Because this Count is the subject of Watson's pending motion to dismiss, no further response is required. To the extent a response is deemed required, Watson denies the allegations of this count.

COUNT IX [sic]: INFRINGEMENT OF THE '306 PATENT

158. Plaintiffs repeat and reallege the allegations of paragraphs 1-157 as though fully set forth herein.

ANSWER:

Watson repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

159. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '306 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Watson admits that it filed ANDA No. 204952 with the FDA seeking regulatory approval of Watson's Proposed Product. Watson further states that the ANDA speaks for itself, and Watson denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the ANDA. Watson denies any remaining allegations of this paragraph.

160. There is a justiciable controversy between the parties hereto as to the infringement of the '306 patent.

ANSWER:

Watson admits the allegations of this paragraph.

161. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will infringe the '306 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States.

ANSWER:

Watson denies the allegations of this paragraph.

162. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will induce infringement of the '306 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, upon FDA approval of Watson's ANDA, Watson will intentionally encourage acts of direct infringement with knowledge of the '306 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Watson denies the allegations of this paragraph.

163. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Watson will contributorily infringe the '306 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Watson's Proposed Product in the United States. On information and belief, Watson has had and continues to have knowledge that Watson's Proposed Product is especially adapted for a use that infringes the '306 patent and that there is no substantial non-infringing use for Watson's Proposed Product.

ANSWER:

Watson denies the allegations of this paragraph.

164. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Watson's infringement of the '306 patent is not enjoined.

ANSWER:

Watson denies the allegations of this paragraph.

165. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER:

Watson denies the allegations of this paragraph.

166. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Watson denies the allegations of this paragraph.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

Watson denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief, or any relief whatsoever.

AFFIRMATIVE DEFENSES

Watson denies all allegations not expressly admitted herein. Without prejudice to the responses and denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Watson asserts the following defenses:

FIRST AFFIRMATIVE DEFENSE

Watson does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, properly construed claim of United States Patent Nos. 6,472,431 ("the '431 patent"), 6,780,889 ("the '889 patent"), 7,262,219 ("the '219 patent"), 7,851,506 ("the '506 patent"), 8,263,650 ("the '650 patent"), 8,324,275 ("the '275 patent"), 8,461,203 ("the '203 patent"), and 8,772,306 ("the '306 patent") either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

The claims of the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, and the '306 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, 116, and/or 120 thereof.

THIRD AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

FOURTH AFFIRMATIVE DEFENSE

On information and belief, by virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, and the '306 patent, Plaintiffs are estopped from maintaining that any valid claim of the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, and the '306 patent are infringed by Watson.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SEVENTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over portions of the claims asserted against Watson, in particular any claims asserted by Plaintiffs to the extent such claims allege infringement by Watson pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

EIGHTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over the claims asserted against Watson alleging infringement of the '431 patent and the '203 patent by Watson pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (e).

Watson expressly reserves the right to supplement and/or amend its Answer to Plaintiffs' Complaint, including but not limited to supplementation and/or amendment of its defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

COUNTERCLAIMS

Watson Laboratories, Inc. ("Watson") for its Counterclaims against Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Counterclaim-Defendants") alleges as follows:

1. These are counterclaim actions for declaratory judgment of invalidity and/or noninfringement of one or more claims of United States Patent Nos. 6,472,431 ("the '431 patent"), 6,780,889 ("the '889 patent"), 7,262,219 ("the '219 patent"), 7,851,506 ("the '506 patent"), 8,263,650 ("the '650 patent"), 8,324,275 ("the '275 patent"), 8,461,203 ("the '203 patent"), and 8,772,306 ("the ''306 patent).

THE PARTIES

2. Watson is a corporation organized under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. On information and belief, Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

4. On information and belief, Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at One Burlington Road, Fourth Floor, Connaught House, Dublin, Ireland 4.

JURISDICTION

5. This Court has subject matter jurisdiction over these counterclaims for declaratory judgment pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1337(a), 1338, 2201, 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Watson and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

6. The Court has personal jurisdiction over Counterclaim-Defendants based on their filing this lawsuit in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

7. Venue is legally proper in this District under 28 U.S.C. §§ 1391 (b) and (c), 28 U.S.C. § 1400 (b) and 21 U.S.C. § 355(j)(5)(C)(i)(II).

PATENTS-IN-SUIT

8. On information and belief, on October 29, 2002, the United States Patent and Trademark Office ("PTO") issued the '431 patent, entitled "Microbiologically Sound and Stable

Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." According to the information on the face of the patent, the patent was assigned to Orphan Medical, Inc.

9. On information and belief, on August 24, 2004, the PTO issued the '889 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." According to the information on the face of the patent, the patent was assigned to Orphan Medical, Inc.

10. On information and belief, on August 28, 2007, the PTO issued the '219 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." According to the information on the face of the patent, the patent was assigned to Orphan Medical, Inc.

11. On information and belief, on December 14, 2010, the PTO issued the '506 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." According to the information on the face of the patent, the patent was assigned to Jazz Pharmaceuticals, Inc.

12. On information and belief, on September 11, 2012, the PTO issued the '650 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." According to the information on the face of the patent, the patent was assigned to Jazz Pharmaceuticals, Inc.

13. On information and belief, on December 4, 2012, the PTO issued the '275 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." According to the information on the face of the patent, the patent was assigned to Jazz Pharmaceuticals, Inc.

14. On information and belief, on June 11, 2013, the PTO issued the '203 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the

Treatment of Narcolepsy." According to the information on the face of the patent, the patent was assigned to Jazz Pharmaceuticals, Inc.

15. On information and belief, on July 8, 2014, the PTO issued the '306 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." According to the information on the face of the patent, the patent was assigned to Jazz Pharmaceuticals, Inc.

16. On information and belief, Jazz Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 21-196, directed to XYREM®.

17. On information and belief, Jazz Pharmaceuticals, Inc. caused the Food and Drug Administration ("FDA") to list the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, and the '306 patent in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with NDA No. 21-196.

18. By maintaining the listing of the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, and the '306 patent, in the Orange Book, Jazz Pharmaceuticals, Inc. represents that a claim of infringement of the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, and the '306 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §355(b)(1)(G).

WATSON'S ABBREVIATED NEW DRUG APPLICATION

19. Watson filed Abbreviated New Drug Application ("ANDA") No. 204952 seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of a generic version of 500 mg/mL sodium oxybate oral solution. In ANDA No. 204952, Watson certified to the FDA that the '889 patent, the '219 patent, the '506 patent, the '650 patent, the

'275 patent, and the '306 patent are invalid, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Watson's 500 mg/mL sodium oxybate oral solution.

PRESENCE OF A CONTROVERSY

20. On October 29, 2014, Watson notified Counterclaim-Defendants that ANDA No. 204952 included a certification that the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, and the '306 patent are invalid and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Watson's 500 mg/mL sodium oxybate oral solution.

21. On December 11, 2014, Counterclaim-Defendants filed an infringement action purportedly under 35 U.S.C. § 271(e)(2) asserting the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, and the '306 patent against Watson.

22. On information and belief, Counterclaim-Defendants have not caused the FDA to remove the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, and the '306 patent from the Orange Book in connection with NDA No. 21-196.

23. In light of all the circumstances, there has been and is now an actual, substantial, and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court between Watson and Counterclaim-Defendants as to whether the products described in Watson's ANDA No. 204952 infringe any and all of the claims of the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, and the '306 patent, and whether any valid claim of the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, and the '306 patent exists.

COUNT I

Declaratory Judgment of Invalidity of the '431 Patent

24. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

25. The claims of the '431 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

26. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the '431 patent is invalid.

27. Watson is entitled to a declaration that the claims of the '431 patent are invalid.

COUNT II

Declaratory Judgment of Non-Infringement of the '431 Patent

28. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

29. Counterclaim-Defendants have accused Watson of infringing claims of the '431 patent in connection with ANDA No. 204592.

30. Watson denies infringement of any valid, properly construed claim of the '431 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson's ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '431 patent.

31. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the '431 patent in connection with ANDA No. 204592.

32. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson's ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '431 patent either directly or indirectly.

COUNT III

Declaratory Judgment of Invalidity of the '889 Patent

33. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

34. The claims of the '889 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

35. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the '889 patent is invalid.

36. Watson is entitled to a declaration that the claims of the '889 patent are invalid.

COUNT IV

Declaratory Judgment of Non-Infringement of the '889 Patent

37. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

38. Counterclaim-Defendants have accused Watson of infringing claims of the ‘889 patent in connection with ANDA No. 204592.

39. Watson denies infringement of any valid, properly construed claim of the ‘889 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson’s ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘889 patent.

40. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the ‘889 patent in connection with ANDA No. 204592.

41. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson’s ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘889 patent either directly or indirectly.

COUNT V

Declaratory Judgment of Invalidity of the ‘219 Patent

42. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

43. The claims of the ‘219 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

44. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the ‘219 patent is invalid.

45. Watson is entitled to a declaration that the claims of the ‘219 patent are invalid.

COUNT VI

Declaratory Judgment of Non-Infringement of the ‘219 Patent

46. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

47. Counterclaim-Defendants have accused Watson of infringing claims of the ‘219 patent in connection with ANDA No. 204592.

48. Watson denies infringement of any valid, properly construed claim of the ‘219 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson’s ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘219 patent.

49. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the ‘219 patent in connection with ANDA No. 204592.

50. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson’s ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘219 patent either directly or indirectly.

COUNT VII

Declaratory Judgment of Invalidity of the '506 Patent

51. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

52. The claims of the '506 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

53. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the '506 patent is invalid.

54. Watson is entitled to a declaration that the claims of the '506 patent are invalid.

COUNT VIII

Declaratory Judgment of Non-Infringement of the '506 Patent

55. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

56. Counterclaim-Defendants have accused Watson of infringing claims of the '506 patent in connection with ANDA No. 204592.

57. Watson denies infringement of any valid, properly construed claim of the '506 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson's ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '506 patent.

58. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the ‘506 patent in connection with ANDA No. 204592.

59. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson’s ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘506 patent either directly or indirectly.

COUNT IX

Declaratory Judgment of Invalidity of the ‘650 Patent

60. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

61. The claims of the ‘650 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

62. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the ‘650 patent is invalid.

63. Watson is entitled to a declaration that the claims of the ‘650 patent are invalid.

COUNT X

Declaratory Judgment of Non-Infringement of the ‘650 Patent

64. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

65. Counterclaim-Defendants have accused Watson of infringing claims of the '650 patent in connection with ANDA No. 204592.

66. Watson denies infringement of any valid, properly construed claim of the '650 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson's ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '650 patent.

67. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the '650 patent in connection with ANDA No. 204592.

68. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson's ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '650 patent either directly or indirectly.

COUNT XI

Declaratory Judgment of Invalidity of the '275 Patent

69. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

70. The claims of the '275 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

71. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the ‘275 patent is invalid.

72. Watson is entitled to a declaration that the claims of the ‘275 patent are invalid.

COUNT XII

Declaratory Judgment of Non-Infringement of the ‘275 Patent

73. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

74. Counterclaim-Defendants have accused Watson of infringing claims of the ‘275 patent in connection with ANDA No. 204592.

75. Watson denies infringement of any valid, properly construed claim of the ‘275 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson’s ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘275 patent.

76. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the ‘275 patent in connection with ANDA No. 204592.

77. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson’s ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘275 patent either directly or indirectly.

COUNT XIII

Declaratory Judgment of Invalidity of the ‘203 Patent

78. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

79. The claims of the ‘275 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

80. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the ‘275 patent is invalid.

81. Watson is entitled to a declaration that the claims of the ‘275 patent are invalid.

COUNT XIV

Declaratory Judgment of Non-Infringement of the ‘203 Patent

82. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

83. Counterclaim-Defendants have accused Watson of infringing claims of the ‘203 patent in connection with ANDA No. 204592.

84. Watson denies infringement of any valid, properly construed claim of the ‘203 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson’s ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘203 patent.

85. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the ‘203 patent in connection with ANDA No. 204592.

86. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson’s ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ‘203 patent either directly or indirectly.

COUNT XV

Declaratory Judgment of Invalidity of the ‘306 Patent

87. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

88. The claims of the ‘306 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

89. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the ‘306 patent is invalid.

90. Watson is entitled to a declaration that the claims of the ‘306 patent are invalid.

COUNT XVI

Declaratory Judgment of Non-Infringement of the ‘306 Patent

91. Watson repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

92. Counterclaim-Defendants have accused Watson of infringing claims of the '306 patent in connection with ANDA No. 204592.

93. Watson denies infringement of any valid, properly construed claim of the '306 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson's ANDA No. 204592 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '306 patent.

94. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the '306 patent in connection with ANDA No. 204592.

95. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson's ANDA No. 204952 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '306 patent either directly or indirectly.

PRAYER FOR RELIEF

WHEREFORE, Watson prays that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

a) Declaring that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson's ANDA No. 204952 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, and the '306 patent;

b) Finding that Watson has not and will not infringe any valid patent claim of the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the

‘203 patent, and the ‘306 patent and whether any valid claim of the ‘431 patent, the ‘889 patent, the ‘219 patent, the ‘506 patent, the ‘650 patent, the ‘275 patent, the ‘203 patent, and the ‘306 patent exists;

c) Finding that no claim ‘431 patent, the ‘889 patent, the ‘219 patent, the ‘506 patent, the ‘650 patent, the ‘275 patent, the ‘203 patent, and the ‘306 patent is valid;

d) Declaring that each claim of the ‘431 patent, the ‘889 patent, the ‘219 patent, the ‘506 patent, the ‘650 patent, the ‘275 patent, the ‘203 patent, and the ‘306 patent is invalid;

e) Granting Watson judgment in its favor on Counterclaim-Defendants’ claims;

f) Granting Watson judgment in its favor on its counterclaims;

g) Denying Counterclaim-Defendants’ request for injunctive relief;

h) Dismissing Counterclaim-Defendants’ Complaint with prejudice;

i) Finding this case exceptional under 35 U.S.C. § 285 and awarding Watson its costs and reasonable attorneys’ fees; and

j) Awarding such further relief as the Court deems just and proper.

Dated: March 23, 2015

s/Liza M. Walsh
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(312) 819-1900

Attorneys for Defendant
Watson Laboratories, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matters captioned, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(MAH), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al.*, Civil Action No. 13-391 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 14-3235 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd., et al.*, Civil Action No. 14-4467 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 14-5139 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 14-6150 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Ranbaxy Laboratories Ltd., et al.*, Civil Action No. 14- 6151 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 15- 173 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd., et al.*, Civil Action No. 15-187 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 15-1043 (ES)(JAD), and *Jazz Pharmaceuticals, Inc., et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-1360 (ES)(JAD) are related to the matter in controversy because they involve defendants who filed Abbreviated New Drug Applications seeking to market generic versions of the same drug product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: March 23, 2015

s/Liza M. Walsh
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LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration.

Dated: March 23, 2015

s/Liza M. Walsh
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